## SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>GABAPENTIN, USP/EP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>2461</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc.</td>
</tr>
</tbody>
</table>

**Supplier Details:**
- MEDISCA Inc.
  - Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
  - 661 Route 3, Unit C, Plattsburgh, NY, 12901
  - 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
  - 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063

- MEDISCA Pharmaceutique Inc.
  - Tel.: 1.800.665.6334 | Fax.: 514.338.1693
  - 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
  - 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2

- MEDISCA Australia PTY LTD
  - Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
  - Unit 7, Heritage Business Park
  - 5-9 Ricketty Street, Mascot, NSW 2020

- MEDISCA UK Limited
  - Tel.: 0800.029.4641
  - 33 St. James's Square, London, United Kingdom SW1Y 4JS

**EMERGENCY PHONE:**
- CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
- NSW Poisons Information Centre: 131 126
- National Chemical Emergency Centre 44(0)1235239670

**USES**
- Anticonvulsant; analgesic.

## SECTION 2: HAZARDS IDENTIFICATION

**GHS CLASSIFICATION**
- Acute Aquatic Toxicity (Category 3)

**PICTOGRAM**
- Not Applicable

**SIGNAL WORD**
- Not applicable

**HAZARD STATEMENT(S)**
- Harmful to aquatic life.

**ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS**
- Not applicable

**PRECAUTIONARY STATEMENT(S)**
- **Prevention:** Avoid release to the environment.
- **Response:** Not applicable
- **Storage:** Not applicable
- **Disposal:** Dispose of contents and/or container in accordance with local regulations.

**HMIS CLASSIFICATION**
- **Health Hazard:** 1
- **Flammability:** 0
- **Reactivity:** 0
- **Personal Protection:** E
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>Cyclohexaneacetic acid, 1-(aminomethyl)-</th>
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<tbody>
<tr>
<td>BOTANICAL NAME</td>
<td>Neurontin</td>
</tr>
<tr>
<td>SYNONYM</td>
<td></td>
</tr>
<tr>
<td>CHEMICAL FORMULA</td>
<td>CaH17NO2</td>
</tr>
<tr>
<td>CAS NUMBER</td>
<td>60142-96-3</td>
</tr>
<tr>
<td>ALTERNATE CAS NUMBER</td>
<td>Not applicable</td>
</tr>
<tr>
<td>MOLECULAR WEIGHT</td>
<td>171.238</td>
</tr>
</tbody>
</table>

**COMPOSITION**

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES**

Chemical family: Cyclohexane-acetic acid derivative.

SECTION 4: FIRST-AID MEASURES

**IN CASE OF EYE CONTACT**
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT**
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

**IF SWALLOWED**
Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

**IF INHALED**
Not expected to present a significant hazard under anticipated conditions of normal use.

**SYMPTOMS AND EFFECTS**

SECTION 5: FIREFIGHTING MEASURES

**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Dust explosion properties:
Kst: 270 bar.m/s
Minimum ignition energy (MIE) - dust cloud: < 3 mJ

**FLAMMABLE PROPERTIES**
May be combustible at high temperature

**HAZARDOUS COMBUSTION PRODUCTS**
Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE EXTINGUISHING MEDIA**
Small fire: dry chemical, CO2 or water spray. Large fire: dry chemical, CO2, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS**
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS**
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
SAFETY DATA SHEET

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS
See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE
Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture.

SPECIFIC END USE(S)
See Section 1

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: GABAPENTIN    CAS #: 60142-96-3

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
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<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td></td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>GESTIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Thermal Hazards: For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES
USP: ELV: Industrial: TWA: 1200 µg/m³
# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>White or almost white, crystalline powder.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Sparingly soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride. It dissolves in dilute acids and dilute solutions of alkali hydroxides.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Boiling Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Explosive Limit</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>log P (OCTANOL-WATER)</strong></td>
<td>-1.31 (20°C)</td>
</tr>
<tr>
<td><strong>Lower Flammable/Explosive Limit(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Melting/Freezing Point</strong></td>
<td>(162 - 167°C, 323.6 - 332.6°F)</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Oxidizing Property</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>6.5 - 8 (2%)</td>
</tr>
<tr>
<td><strong>Relative Density (Water = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Upper Flammable/Explosive Limit(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Density (Air = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>&lt; 0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not available</td>
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The physical data presented above are typical values and should not be construed as a specification.

# SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not established.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Stability</td>
<td>Stable under recommended storage conditions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>Strong oxidants.</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reaction</td>
<td>Not established.</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Moisture, sunlight and extreme temperatures.</td>
</tr>
</tbody>
</table>

# SECTION 11: TOXICOLOGICAL INFORMATION
### SAFETY DATA SHEET

#### ACUTE TOXICITY
- Oral: Rat: LD50: (mg/kg): > 5000
- Dermal: Rabbit: LD50: (mg/kg): Not available
- Inhalation: Rat: LC50: (mg/L/4hr): Not available

#### SKIN CORROSION/IRRITATION
Due to lack of data the classification is not possible.

#### SERIOUS EYE DAMAGE/EYE IRRITATION
Based on available data, the classification criteria are not met.

#### RESPIRATORY SENSITIZATION
Data from germ cell mutagenicity tests were not found.

#### SKIN SENSITIZATION
Based on available data, the classification criteria are not met. Suspected skin sensitizer: CAESAR skin sensitisation model in VEGA Q(SAR) platform predicts that the chemical is a Sensitizer (moderate reliability).

#### GERM CELL MUTAGENICITY
Due to lack of data the classification is not possible.

#### CARCINOGENICITY
- OSHA: GABAPENTIN is not listed.
- NTP: GABAPENTIN is not listed.
- IARC: GABAPENTIN is not evaluated.
- California Proposition 65: This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

#### ADDITIONAL CARCINOGENICITY INFORMATION
Based on available data, the classification criteria are not met. Suspected carcinogen: CAESAR Carcinogenicity model in VEGA Q(SAR) platform predicts that the chemical is Carcinogen (EXPERIMENTAL value); ISS Carcinogenicity model in VEGA Q(SAR) platform predicts that the chemical is Carcinogen (EXPERIMENTAL value); carcinogen according to ISSCAN.

#### REPRODUCTIVE TOXICITY
- Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA Q(SAR) platform predicts that the chemical is Toxicant (good reliability).

#### SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Due to lack of data the classification is not possible.

#### SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Due to lack of data the classification is not possible.

#### ASPIRATION HAZARDS
Symptoms related to the physical, chemical, and toxicological characteristics:
- Unsteadiness.
- Uncontrolled eye movements.
- Visual disturbances.
- Dizziness.
- Drowsiness.
- Tiredness.
- Muscle pain.
- Back pain.
- Swelling of face or extremities.
- Twitching.
- Memory loss.
- Mood or behavior changes.
- Slurred speech.
- Frequent, painful, or difficult urination.
- Constipation.
- Indigestion.
- Nausea.
- Diarrhea.
- Vomiting.
- Abdominal pain.
- Headache.
- Decreased sexual desire.
- Difficulty sleeping.
- Runny nose.
- Dry mouth.
- Sore throat.
- Ringing in ears.
- Weight gain.
- Delayed and immediate effects of exposure:
- High blood pressure.
- Medical conditions aggravated by exposure:
- Active alcoholism.
- Diabetes.
- Impaired kidney function.

#### POTENTIAL HEALTH EFFECTS
- **Inhalation**: May be harmful if inhaled. May cause respiratory tract irritation.
- **Ingestion**: May be harmful if swallowed.
- **Skin**: May be harmful if absorbed through skin. May cause skin irritation. May cause allergic reaction.
- **Eyes**: May cause eye irritation.

### SECTION 12: ECOLOGICAL INFORMATION
SAFETY DATA SHEET

TOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): 29.88*
EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Log Pow: -1.31 (20°C).

MOBILITY IN SOIL

Water Solubility: 4490 mg/L (25°C)
Henry’s Law Constant: 1.81E-10 atm-m³/mole (25°C)

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment.

NOTES

*Fish Acute Toxicity model (KNN/Read-Across) in VEGA (Q)SAR platform prediction (good reliability).

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA

HAZCHEM

Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not Listed

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>GABAPENTIN 60142-96-3</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS
SAFETY DATA SHEET

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

ABBREVIATIONS AND ACRONYMS

LAST REVISION
06/2019

SUPRESEDES
12/2018

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION
For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.